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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,476	07/26/2006	Elvir Causevic	KEDI 8309 W1	5338

1688 7590 04/30/2008

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,476	CAUSEVIC, ELVIR	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5, 9-15, 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Meyerson et al (6,589,189 B2).

Meyerson et al disclose a noninvasive means for monitoring a patient and further disclose a plurality of independently operable modular testing subsystems, the subsystems comprising at least: an auditory response testing subsystem, configured to measure a response of the patient to an auditory stimulus, the response being representative of a first indicator; at least one non-auditory response testing subsystem configured to measure at least one characteristic of the patient, the characteristic being representative of at least one additional indicator of the at least one disorder; a processor system coupled to each of the modules, the processor system being configured with a computer program to selectively operate each of the module testing subsystems and to generate an index value representative of the at least one disorder responsive to a plurality of indicators of the at least one disorder generated by at least two of the modular testing subsystems; a blood analysis subsystem; at least a first connection point on the enclosure for coupling at least a first instrument to the auditory

response testing subsystem; at least a second connection point on the enclosure for coupling at least a second instrument to the at least one non-auditory response testing subsystem; a power supply; the first and second instruments are selected from microphones, acoustic emitters, electrodes, gas analyzers and optical sensors; the at least one non-auditory response subsystem includes a bioelectric signal measurement subsystem, the bioelectric signal measurement subsystem being configured to measure at least one bioelectric signal from the patient; the processor is configured to evaluate the bioelectric signal to detect at leas tone anomaly representative of a medical disorder in the patient; the bioelectric signals include EEG signals or ECG signals; the processor is configured to selectively display test results from a single testing subsystem; and the processor is configured to selectively display a cumulative index generated from measurements acquired by a plurality of testing subsystems, the cumulative index being representative of a medical condition of the patient. See Figures 3, 4 and 8; Column 8, lines 62-67; Column 9, lines 1-4 and 15-16; Column 10, lines 50-67; Column 11, lines 1-3 and 58-64.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyerson et al (6,589,189 B2) as applied to claim 1 above, and further in view of Smits et al (6,544,190 B1).

Meyerson et al, as discussed above, disclose a means for obtaining measurements from a patient but fail to disclose the at least one non-auditory response testing subsystem includes a breath gas monitoring subsystem; the breath gas monitoring subsystem is configured to measure at least a concentration of carbon monoxide from the patient, the carbon monoxide concentration being an indicator of a hemolysis condition; the breath gas monitoring subsystem is configured to measure a concentration of breath gas from the set of oxygen, carbon dioxide, nitrous oxide and nitrous dioxide.

Smits et al, as discussed above, disclose a means for analyzing breath gas, and further disclose the at least one non-auditory response testing subsystem includes a breath gas monitoring subsystem; the breath gas monitoring subsystem is configured to measure at least a concentration of carbon monoxide from the patient, the carbon monoxide concentration being an indicator of a hemolysis condition; the breath gas monitoring subsystem is configured to measure a concentration of breath gas from the set of oxygen, carbon dioxide, nitrous oxide and nitrous dioxide. See Column 3, lines 16-19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Meyerson et al to include the use of a

breath gas analyzer, as per the teachings of Smits et al, since it would provide an additional means of analyzing the condition of the patient.

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyerson et al (6,589,189 B2) as applied to claim 1 above, and further in view of Mault et al (2003/0208113 A1).

Meyerson et al, as discussed above, disclose a means for measuring parameters of a patient, but fail to disclose the blood analysis subsystem is configured to measure the presence or absence of at least one chemical compound indicative of a hemolysis condition of the patient; and the blood analysis subsystem is further configured for noninvasive optical blood analysis.

Mault et al discloses a blood analyte monitoring system and further disclose the blood analysis subsystem is configured to measure the presence or absence of at least one chemical compound indicative of a hemolysis condition of the patient; and the blood analysis subsystem is further configured for noninvasive optical blood analysis. See Paragraphs 0201, 0203 and 0204. Lactate concentration in the blood is an indicator of hemolysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Meyerson et al to include the use of a blood analyte monitoring means, as per the teachings of Mault et al, since it would provide an additional means of monitoring parameters of a patient to determine a medical condition.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyerson et al (6,589,189 B2) and Mault et al (2003/0208113 A1) as applied to claim 7 above, and further in view of Jay et al (2004/0138539 A1).

Meyerson et al and Mault et al, as discussed above, disclose a means for monitoring blood parameters to determine a medical condition but fail to disclose the blood analysis subsystem is configured to measure at least a presence or absence of at least one chemical compound indicative of a lactose malabsorption condition of the patient.

Jay et al disclose blood monitor and further disclose the blood analysis subsystem is configured to measure at least a presence or absence of at least one chemical compound indicative of a lactose malabsorption condition of the patient. See Paragraph 0064. The measurement of lactose in the bloodstream would provide an indicator of the absorption of lactose by the body.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Meyerson et al and Mault et al to include the ability to measure the lactose concentration in the blood, as per the teachings of Jay et al, since it would provide a means of monitoring an additional parameter of the patient.

7. Claims 16-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyerson et al (6,589,189 B2) in view of Mault et al (2003/0208113 A1).

Meyerson et al, as discussed above, disclose a means for monitoring the condition of a patient, and further disclose a portable handheld enclosure; a plurality of

testing subsystems; at least one connection point on the enclosure for coupling at leas tone instrument to the testing subsystem; a power supply; a processor coupled to each of the testing subsystems, the processor configured with a computer program to selectively operate each of the plurality of te4sting subsystems and to generate an index value representative of the at least one medical disorder responsive to a plurality of indicators generated by at least two of the testing subsystems; an auditory screening subsystem, a breath analyzer, and a bioelectric signal measurement subsystem; a blood analysis subsystem; at least one of the instruments is selected from the group of microphones, acoustic emitters, electrodes, gas collectors and optical sensors; and a display. See Figures 3, 4 and 8; Column 8, lines 62-67; Column 9, lines 1-4 and 15-16; Column 10, lines 50-67; Column 11, lines 1-3 and 58-64.

Meyerson et al however fail to disclose monitoring the patient for the medical condition of hemolysis.

Mault et al, as discussed above, disclose a blood analysis means and further disclose monitoring a medical condition including hemolysis. See Paragraphs 0201, 0203 and 0204. Lactate concentration in the blood is an indicator of hemolysis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Meyerson et al to include the use of a blood analyte monitoring means, as per the teachings of Mault et al, since it would provide an additional means of monitoring parameters of a patient to determine a medical condition.

Response to Arguments

8. Applicant's arguments, filed January 17, 2008, with respect to Causevic et al (6,866,639 B2) have been fully considered and are persuasive. The rejection of Causevic et al (6,866,639 B2) has been withdrawn.

9. Applicant's arguments filed January 17, 2008 have been fully considered but they are not persuasive. The Applicants argue that Meyerson et al fail to disclose the currently amended independent claims because Meyerson et al fail to disclose a means for generating an index value representative of a disorder using combined data from more than one testing subsystem. Meyerson et al disclose a means for determining the intracranial pressure utilizing otoacoustic emission tests as well as other various types of sensing means to validate the intracranial pressure measurement. The validation of the measurement of the intracranial pressure constitutes the creation of an index value because an index is defined as "something that leads one to a particular fact or conclusion", as defined by Merriam Webster Online dictionary. Therefore, the claimed index value is nothing more than the disclosed validation in Meyerson et al.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., generating an index value representative of a disorder using combined data from more an one response testing subsystem) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Patent Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736